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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.
1300 19TH STREET, N.W.
SUITE 600
WASHINGTON,, DC 20036

EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	5

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	10/087,942	CAMPBELL ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/16/02* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-127* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 and 18-30 drawn to a method of identifying a culture medium component.

II. Claims 31-35, drawn to a method of defining a test compound library.

III. Claims 36-40, drawn to libraries of virtual molecules.

IV. Claims 41-54 and 57-58, drawn to a method of identifying a culture media component.

V. Claims 16-17, 55-56 and 113-118, drawn to culture media and culture media components.

VI. Claims 59-73, drawn to a method of predicting an indicia property of a peptide.

VII. Claims 74-95, drawn to methods of identifying peptides with a predicted indicia of activity.

VIII. Claims 96-112 and 127, drawn to a method of identifying a culture media component.

IX. Claims 119-122 and 123-126, drawn to an apparatus for identifying a culture media component (which has been

interpreted as a programmed computer recited in means plus function language), and computer program.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions contain different process steps, modes of operations and effects. For example, the method of Group IV requires defining a first test library not required by the other two methods. The method of Group VIII requires the culturing of a first and second groups of cell not required by the other groups of molecules.

Inventions I, IV, VIII and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions contain different steps and produce different results i.e., defined culture media components and a test compound library.

Inventions I, IV, VIII and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as the methods do not produce the product, it is produced by the method of group II.

Inventions I, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the components of group V can be used in a materially different processes such as in the preparation of vitamins or dietary supplements of animals.

Inventions (I, IV and VIII) and (VI and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different process steps. For example, group VI and VII are directed to predicting the

property of a peptide not within a group of test peptides. The methods of groups I, IV and VIII are drawn to identifying cell culture media components. Moreover, the method of groups I, IV and VIII do not require the methods of Groups VI and VII. For example, the methods of groups VI and VII can be practiced with test compounds predicted based upon relationships using less than whole molecule parameters (e.g., a partial string, a partial COMFA field etc.)

Inventions I, IV, VIII and IX are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by hand.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by constructing a combinatorial library of compounds, screening it and determining which of the

compounds present in the library has the optimal activity of a specific indicator and using it as the lead compound.

Inventions II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process make a different product which is a test compound library.

Inventions II and VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different process steps and produce different results. For example, the method of group II selects a library based upon a relationship of compounds with isomers of that compound to select a subset of compounds where the method of group IV is directed to predicting an indicia property of peptides based upon at least one whole molecule parameter and measurements thereof. Group VII is directed to a method of

identifying a peptide using a first and second peptide libraries.

Inventions II, VI and VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes can be practiced by hand.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products, a library of molecules and a culture media compound. The inventions are distinct, as the libraries comprise different components than the single media components. Moreover, the libraries can be used in alternative methods of screening.

Inventions (VI and VII) and (III and V) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made

by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group III can be made by combinatorial library of compounds, screening the library and determining which of the compounds present in the library have the activity. The active compounds can be assembled into a library as required by group III. The methods therefore require different steps.

Inventions (III and V) and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to different products. The products of group III and V can be made without the computer or program of group IX. Moreover, the products can be operated without the invention of group IX. For example, in screening, testing and other processes.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different processes that require

different steps and results. For example the step of identifying a second peptide library as recited in group VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-IX, specifically the literature searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If applicants elect group I, applicants are required to elect from the following species:

A. Function for performing the method (e.g., f(x) setting forth all variables).

B. Parameters (e.g., claim 15)

C. Test Libraries (e.g., claim 18)

D. Plurality of cell cultures, including or excluding the forming step (e.g., claim 23). If the process is to include this step then further election of a specific measured property is required i.e., as specific election of production of specific compounds e.g., estrogen (not the generic steroids, carbohydrates and other generic compounds). Also, specifically altered peptide e.g., trypsin.

A proper election of species requires a selection from each subgenus A-D. Currently claim 1 is generic and will be examined with any of the species elected.

If applicants elect group II, applicants are to elect form the following species:

A. Test libraries (e.g., as recited in claim 34)

B. Space-filling (e.g., claim 32 i.e., if including or excluding the use of space-filling techniques).

A proper election of species requires a selection from each subgenus A-B. Currently claim 31 is generic and will be examined with any of the species elected.

If applicants elect group III, applicants are to elect form the following species:

A. Test libraries

Currently claim 31 is generic and will be examined with any of the species elected.

If applicants elect group IV, applicants are to elect form the following species:

A. Functions for performing the method.

B. Parameters (e.g., specific whole molecule parameter such as charge or molecular weight).

C. Compound space (e.g., recited in claim 53)

A proper election of species requires a selection from each subgenus A-C. Currently claim 41 is generic and will be examined with any of the species elected.

If applicants elect group V, applicants are to elect a specific culture medium component e.g., election by structure.

If applicants elect group VI, applicants are to elect form the following species:

A. Whole molecule parameters as to the number and type (e.g. claims 62 and 64).

B. Test peptides specific activity (e.g., induction of beta lactamase or beta receptor expression).

A proper election of species requires a selection from each subgenus A-B. Currently claim 59 is generic and will be examined with any of the species elected.

If applicants elect group VII, applicants are to elect from the following species:

A. Functions (e.g., claim 80)

B. Parameters (e.g., claims 83-86)

C. Specific activity of the test peptides.

A proper election of species requires a selection from each subgenus A-C. Currently claim 79 is generic and will be examined with any of the species elected.

If applicants elect group VIII, applicants are to elect from the following species:

A. Defined and undefined media

B. Media compounds whether included or excludes (e.g., claims 97-99).

C. Protein component (undefined)(e.g., claims 102-104).

D. Property measured. (e.g., claims 108-112, i.e., with a specific compound alteration e.g., estrogen). Also specific protein as trypsin.

A proper election of species requires a selection from each subgenus A-D. Currently claim 96 is generic and will be examined with any of the species elected.

If applicants elect group IX, applicants are to elect a single specific function. (e.g., f(x), setting forth all variables). Also, if the function is of the form d(x1, x2) as recited in claims 122 and 126, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw

October 17, 2003